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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/993,946	12/18/1997	THOMAS A. SILVESTRINI	AT 2036.00	5937

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EXAMINER

WILLSE, DAVID H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/993,946

Applicant(s)

SILVESTRINI, THOMAS A.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7,9-13,15-17,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-13,15-17,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 depends from cancelled claim 8.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 9-11, and 15-17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Peyman, US 5,964,748. Particular attention is directed to column 12, lines 34-40; column 13, lines 32-35; column 15, lines 58-66; and column 17, lines 28-31.

Regarding claim 1 and others, in the embodiment of Figures 37-45 (column 15, line 30 et seq.), a small incision **418** is cut in the anterior surface of the cornea (column 15, lines 42-47), a circular channel originating at one side of the incision **418** is created (column 17, lines 19-31), the circular channel is widened in certain locations to accommodate a ring of non-uniform cross-section (column 18, lines 4-11; column 13, lines 30-39; column 3, lines 58-61; column 17, lines

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28-31; column 21, lines 46-49), and the intracorneal implant **430** is introduced into the widened channel through the small incision **418** (column 16, lines 63-67). The distance from the exposed side of the incision **418** to the circular channel can be 1.5 mm or even less (column 15, lines 43-46; column 17, lines 36-38). As another example, in the embodiment depicted in Figure 89 (column 29, lines 45-58), a relatively small arcuate slit **1118** is formed in the exterior surface of the cornea **1112**, a circular intracorneal channel **1120** is created, the circular channel is widened (column 29, lines 54-55), and "an ocular implant can be inserted into the annular pocket" (column 29, lines 56-57). Regarding claim 2: column 17, lines 36-40; column 12, lines 35-37; and Figures 41-45. Regarding claims 16 and 17: column 16, line 63, through column 17, line 5.

Claims 6, 13, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, US 5,964,748. Side legs as set forth in instant claims 6, 8, and 13 would have been obvious from column 13, lines 32-35, and column 15, lines 64-66, in order to accommodate the shape of the ocular material **430** (column 17, lines 28-31; Figure 42), with further motivation having been provided by Figures 27 and 36. Regarding claim 24, the tool **450** being arc-shaped would have been obvious in order to match the circular shape of the pocket **426** and/or a curved incision (column 15, lines 43-44).

Claims 4, 5, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, US 5,964,748, in view of Mathis et al., US 5,846,256. To employ the clockwise and counter-clockwise dissectors and channel connectors taught in Mathis et al. would have been obvious in order to provide better matching of the circular intracorneal channel dimensions with

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those of the ring implant **430** of Peyman, with further motivation to use complementally shaped tools having been provided by column 17, lines 19-22, 28-31, 39-42, and 49-51, of Peyman.

The Applicant's remarks have been reviewed. The Applicant asserts that Peyman "fails to describe a method that utilizes a widened, circular intracorneal channel originating at said incision to insert an intracorneal implant into the channel" (Paper No. 28: page 4, lines 23-25). The term "incision" is defined as "a division of the soft parts made with a knife" (*Stedman's Medical Dictionary*, 26<sup>th</sup> edition, 1995). In the embodiment of Figures 37-45 of Peyman, the circular channel originates at one end or side of the division or incision **418**. Although the figures depict an oblique incision, the Applicant's own invention likewise encompasses such, as seen from page 13, line 13, through page 14, line 11, for example. The Applicant apparently specifically alleges that Peyman "fails to teach or suggest the creation of a circular intracorneal channel" (Paper No. 28: page 5, lines 24-26). The examiner disagrees: a circular channel is evident from Figures 43-45 and from column 17, lines 26-28, for example.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is (703) 308-2903. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse  
May 27, 2003

  
**DAVE WILLSE**  
**PRIMARY EXAMINER**  
**ART UNIT 3738**